# This Page Is Inserted by IFW Operations and is not a part of the Official Record

### **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BÖRDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

### IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents will not correct images, please do not report the images to the Image Problem Mailbox.

## UK Patent Application (19) GB (11) 2 199 247(19)

(43) Application published 6 Jul 1988

- (21) Application No 8628605
- (22) Date of filing 29 Nov 1986
- (71). Applicant Femcare Limited

(Incorporated in United Kingdom)

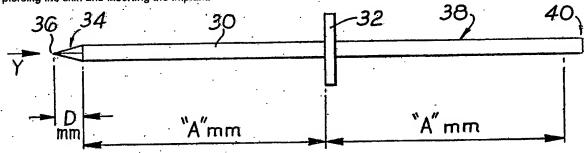
Bar Lane, Industrial Park, Bar Lane, Basford, Nottingham, NG6 0JA

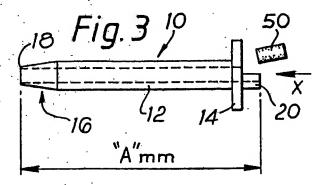
- (72) Inventor Gilbert Marcus Flishle
- (74) Agent and/or Address for Service. Eric Potter & Clarkson 14 Oxford Street, Nottingham, NG1 5BP

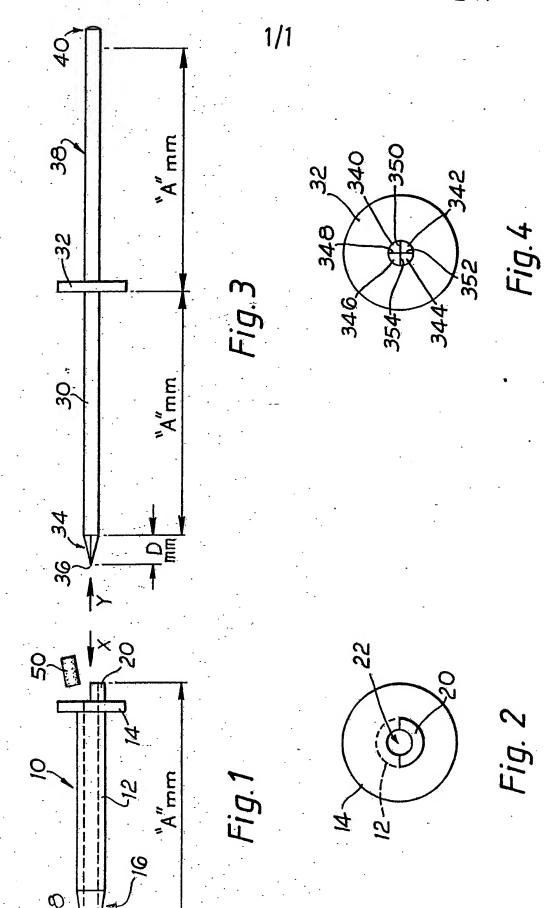
- (51) INT CL A61B 17/34 A61M 25/00
- (52) Domestic classification (Edition J): A5R GB
- (56) Documents cited None
- (58) Field of search Selected US specifications from IPC sub-classes A61B A61M

#### (54) Subcutaneous implantation equipment

(57) Disposable equipment for subcutaneous implantation of for example hormone implants (50) comprises a cannula and a combined trocar and obturator (30) winch is reversible within the cannula to perform the respective functions of piercing the skin and inserting the implant.







## IMPROVEMENTS IN OR RELATING TO SUBCUTANEOUS IMPLANTATION EQUIPMENT

The present invention relates to subcutaneous implantation equipment and more particularly to equipment for the implantation of hormone implants into the fat layer beneath the skin.

Known equipment comprises a cannula and a trocar the trocar and cannula being pushed through the skin wall, the skin having been previously incised with a scalpel to ease their entry. The trocar is then removed and an oestradiol implant is placed into the end of the cannula and pushed down the cannula with an obturator. The various parts, cannula, trocar and obturator are made from surgical quality stainless steel and are sterilised betwen operations.

The disadvantages of the known equipment is that it is relatively expensive to produce and because it requires sterilising between operations the number of operations is limited by the quantity of equipment available. The sterilisation of multi-use equipment is in any case always hazardous because, if incomplete there is an infection risk e.g. transmission of AIDS

It is an object of the present invention to provide equipment for subcutaneous implantation of hormones which is relatively inexpensive to produce and which is therefore disposable. It is also an object of the present invention to provide such equipment which is simple in design and construction and is therefore easily moulded in a suitable plastics material.

The present invention therefore provides equipment for the subcutaneous implantation of hormone implants comprising a cannula and a combined trocar and obturator.

preferably the various parts are all made from a plastics material. The cannula preferably comprises an elongate tube which is preferably provided with a collar

30

at a position along its length, the tube being reduced in wall thickness at one end to provide a reduced area for entry through the skin and in which the wall of the tube is cut away at the other end on the other side of the collar to provide an entry for the implant.

Preferably the combined trocar and obturator comprises an elongate rod provided with a collar at a central position, one end of the rod being sharpened to provide a reduced area for entry through the skin and thereby forming the trocar and the other end being substantially flat to form the obturator.

10

15

20

30

35

Preferably the collars are formed integrally by plastic injection moulding of the parts.

Preferably the sharpened end is formed with four or more faces to provide easier penetration of the skin.

Preferably the cannula trocar and obturator are circular in cross-section and the collars are annular.

Embodiments of the present invention will now be described, by way of example with reference to the accompanying drawings in which:-

Figure 1 shows in side elevation a cannula according to the present invention;

Figure 2 shows the cannula of Figure 1 in end elevation;

25 Figure 3 shows a combined trocar and obturator according to the present invention; and

Figure 4 shows the combined trocar and obturator of Figure 3 in end elevation.

With reference now to Figure 1, the cannula 10 comprises a tube 12 provided with a collar 14. One end 16 of the tube is reduced in wall thickness to provide a sharp front edge 18. The other end of tube 12 on the opposite side of collar 14 is provided with a "cut away" portion 20 which provides an entry or loading "gate" for an implant pellet. The tube 12 and collar 14 are

preferably of circular cross-section as shown in Figure 2 which is an end view in direction X. The tube and collar could however be made of any other suitable cross-section such as oval or square etc.

With reference now to Figures 3 and 4 the combined trocar and obturator is shown and comprises a rod 30 with collar 32 positioned substantially at a central position as indicated by dimension "A" mm. The rod 30 is dimensioned to pass down the central hole in the cannula 10.

5

10

15

25

At one end rod 30 is provided with a reduced area 34 providing a pointed end 36. The reduced area 34 (see Figure 4 view in direction Y) is in the embodiment shown provided by four facets 340, 342, 344; 346 which provide cutting edges 348, 350, 352, 354 in addition to the point 36. The end 36 may be alternately provided with only three facets or may be of the chisel shape, each design providing a suitable shaped end to assist entry. forms the trocar which when inserted into the cannula 20 protrudes a distance D mm equal to the length of the reduced area 34 because the length of the cannula is also The combination of sharp point 36, cutting edges 348, 350, 352 and 354 and front edge 18 provides relatively easy penetration of the skin (which has preferably previously been prepared by a small scalpel incision).

The other end 38 of rod 30 on the opposite side to collar 32 is provided with a relatively flat end 40 which may be square or slightly rounded as shown. The length of the rod 38 is slightly greater than dimension "A" mm as shown.

In use, once the skin has been prepared and a small incision made by a scalpel the trocar 30, 34, 36 is inserted into the cannula 10 and the point 36 will protrude a distance D mm from the end 18 and the cannula and trocar, being gripped by the surgeon by collars 14 and 32 may be forced through the skin to leave end 18 protruding a short distance into the fatty layer under the skin.

The trocar is then withdrawn from the cannula, a hormone pellet 50 (Figure 1) is dropped into the loading "gate" 22. The rod 30 is reversed, the blunt end 38 being used as an obturator to push the pellet 50 down the cannula tube 12 and out into the fatty layer, the collar 32 providing a stop for the obturator. The cannula and obturator are then withdrawn and a suitable plaster applied to the wound in known manner.

The equipment according to the present invention provides a two piece replacement for the existing cannula, trocar and obturator and may be injection moulded in a plastics material. Point 36 can be formed as an integral part of the moulding or, may be machined as a separate operation to provide very sharp cutting edges.

The equipment is therefore relatively inexpensive and may be packaged in a sterile manner for opening and then for disposal once an operation has been performed. This therefore overcomes any need for sterilising the previous equipment.

25

5

10

15

20

. . . .

30

#### CLAIMS

- I. Equipment for the subcutaneous implantation of hormone implants comprising a cannula and a combined trocar and obturator.
- Equipment as claimed in Claim 1 in which the cannula
  and combined trocar and obturator are all made from a plastics material.
- 3. Equipment as claimed in Claim 1 or Claim 2 in which the cannula comprises an elongate tube which is provided with a collar at a position along its length, the tube 10 being reduced in wall thickness at one end to provide a reduced area for entry through the skin and in which the wall of the tube is cut away at the other end on the other side of the collar to provide an entry for the implant.
- 4. Equipment as claimed in any one of Claims 1 to 3 in which the combined trocar and obturator comprises an elongate rod provided with a collar at a central position, one end of the rod being sharpened to provide a reduced area for entry through the skin and thereby forming the trocar and the other end being substantially flat to form the obturator.
  - 5. Equipment as claimed in Claim 4 in which the collars are formed integrally by plastic injection moulding of the parts.
- 25 6. Equipment as claimed in Claim 4 or Claim 5 in which the sharpened end is formed with four or more faces to provide easier penetration of the skin.
- 7. Equipment as claimed in any one of the preceding claims in which the cannula trocar and obturator are 30 circular in cross-section and the collars are annular.
  - 8. Equipment for the subcutaneous implant of hormone implants substantially as described with reference to the accompanying drawings.